**UBC BC Cancer Research Ethics Board**

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# RESEARCH ETHICS ARTIFICIAL INTELLIGENCE / MACHINE LEARNING APPLICATION SUBMISSION CHECKLIST

The purpose of this checklist is to highlight key items in the evaluation of the ethical acceptability and privacy-related information of a research application which involves the use and/or development of AI/ML algorithms. Please address each topic described below as applicable for your specific application and attach to Section 9.8 on the RISe application. If any of these categories are not applicable to your specific AI/ML application, please indicate this with “N/A” and a brief explanation.

**PURPOSE AND CONTEXT OF THE ALGORITHM**

*Here, we are seeking information on how the future intended use of the algorithm.* Please describe:

* The specific clinical function of the algorithm (ie. Treatment response, diagnostics, improved efficiency):
* The target population and clinical setting:
* The intended method of clinical implementation:
* Is this application for the development of a new algorithm or is this application proposing the use of a previously developed algorithm?

**QUALITY OF DATA USED FOR ALGORITHM TRAINING / VALIDATION**

For the respective training and/or validation dataset, please describe:

* All datasets will inherently contain specific biases (ie. Selection bias, systematic bias, such as demographics, rural vs urban population, etc). Please describe the population used in the training and/or validation dataset and consider and acknowledge any bias this dataset my contain, such as underrepresented demographics in the training or evaluation datasets*.* 
  + Note: It is important to acknowledge these biases in the interpretation of study results
* The population used in the training and/or validation dataset and (dataset bias must be addressed by the study team):
* The degree of missing data in the training and/or validation dataset and how this was/will be handled:

* How accessible the training and/or validation dataset is (i.e. open access/restricted use data?):
* The interoperability of the algorithm between different technological platforms:
* If the training and/or validation dataset is able to be stored and reused:
* How reliable the labeling of the training and/or validation data was or is expected to be:

**MODEL PERFORMANCE**

* Please describe the internal validation and external validation steps and justify the performance assessment values that were or will be used in this algorithm:
* In the event of the algorithm failing, how will this impact the various groups involved (ie patient, clinician, hospital, etc):

**CLINICAL INTERPRETABILITY OF MODEL OUTPUTS**

* Please clearly list the labels and predictors of the dataset:
* Please explicitly state if an explanation exists for how the predictions were generated, and if the model decision process is transparent, or if a black box model will be used:
* Please describe how model predictions were/will be generated. Please state if this application describes the use of supervised, unsupervised, semi-supervised algorithms:

**PROJECTED FIT OF THE ALGORITHM INTO CURRENT WORKFLOWS**

* Please describe how the algorithm is expected to fit and complement the current clinical workflow, including when the algorithm would be applied, the degree of training of clinical staff needed for future implementation:
* Please describe how easy it is to use the algorithm in the recommended way and also consequences of using it in an unintended or wrong way. Please include details on the recommended use (i.e. one piece of evidence in a more holistic assessment or a definite decision tool to automate a process):

**MODEL TRANFERRABILITY TO PROJECTED FUTURE CLINICAL SETTING**

* Please describe how the algorithm is expected to perform in different clinical settings, such as varying population characteristics, different medical equipment, etc and any efforts to adapt it to new settings:

**EVIDENCE FOR IMPROVED PATIENT CARE AND OUTCOMES FROM USE OF THE ALGORITHM**

* Please describe if this algorithm has been previously used, and if so, its effect on clinical care:

**DETRIMENTAL PREDICTIONS OF THE ALGORITHM**

* Please consider all potential detrimental effects in use of the algorithm in the context described in this application and describe bias mitigation strategies, i.e. the efforts that will be taken to avoid or fix outdated or corrupted datasets or harmful predictions:
* Please comment on how the algorithm would be updated and reviewed after deployment and how difficult this will be to perform:

**ETHICAL, LEGAL OR SOCIAL CONCERNS OF THE ALGORITHM**

Please indicate the following:

* Have participants specifically consented to their data being used for this application, or is a waiver of consent being requested? Please comment on how **participant consent** of the corresponding data will be considered during the development of the algorithm:
* Who takes **responsibility for post-implementation monitoring** of the safety and efficacy of the algorithm:
* **Potential incidental findings** resulting from use of the algorithm and the plan to address these, (ie. unanticipated findings, such as participant re-identification, unexpected information on socioeconomic status, race/ethnicity, etc):
* How the various groups involved would be impacted if the **algorithm is failing**(i.e. patient is sent for unnecessary screening/testing):

**PRIVACY AND SECURITY CONCERNS**

Please indicate the following:

* Is this project being conducted with **partners outside the BC Cancer/PHSA**? And if yes, please describe the data or products shared with these partners and if the TDO been notified about the potential need for an agreement?
* Please clearly state **who will have stewardship of the data** used in the algorithm and if any ownership claims of the data are anticipated:
* Who will **own the intellectual property** pertaining to the algorithm:
* Will this research be **conducted internally** within a pre-vetted BC Cancer or PHSA environment? If not, please describe the environment. Note that new platforms, environments, or activities that have not been vetted for security and privacy compliance and/or aim to connect with Health Authority systems will require a Privacy Impact Assessment (PIA) and security review.

* How **privacy** will be preserved while using the algorithm. Note that Google Collaboratory is not appropriate to use for sensitive data:
* Does each **study site have the resources/equipment** needed to implement this algorithm for the specific target population, or are there any potential concerns regarding including different institutions with implementation and use of this algorithm: